DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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January 8, 2003

WARNING LETTER
CIN-03-14878

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert J. Oschsendorf
President
E-Med Future, Inc.
794 Morrison Road
Columbus, OH 43230

Dear Mr. Oschsendorf:

On August 7-15, 2002, investigators from the Food and Drug Administration (FDA) conducted a pre-approval inspection of your facility and collected information that revealed a serious regulatory problem involving the product known as the "NeedleZap," which is made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device as defined by Section 201 (h) of the Act, 21 U.S.C. § 321(h). The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Although you have now submitted to FDA a premarket approval application [redacted], our records show you did not obtain marketing clearance prior to introducing approximately [redacted] NeedleZap devices into commercial distribution. The devices were labeled for "Law Enforcement Only" and for "Veterinary Use Only." However, the intended use of the device is to destroy needles to protect humans from contamination and disease. Consequently, these devices were not intended to be used for "law enforcement" or "veterinary" purposes.

In addition, there is no exemption that allows marketing this Class III device, which requires general controls and an approved application for a Premarket Approval, to law enforcement agents or veterinarians without the FDA's approval.

Because you do not have marketing clearance from FDA, marketing the NeedleZap is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) of the Act (21 U.S.C. § 351(f)(1)(B)) because you did not obtain premarket approval prior to marketing it.

The FDA inspection also revealed that the methods used in, or the facilities or controls used for, the manufacture, processing, packing, storage or distribution of the approximately 1500 NeedleZap devices that your firm distributed are not in conformance with the requirements of the Quality System Regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

- Failure to establish written procedures for finished device testing and to ensure that finished devices meet all specifications prior to distribution (21 CFR 820.80(d) and 820.160).

- Failure to maintain device history records for the NeedleZap device to demonstrate that the devices are manufactured in accordance with the device master record (21 CFR 820.184).

- Failure to prepare and approve a device master record for the NeedleZap device (21 CFR 820.181).

- Failure to adequately ensure that incoming product is inspected, tested, or otherwise verified as conforming to specified requirements (21 CFR 820.80 (b)).

  For example, the approximately [redacted] NeedleZap devices manufactured and distributed by your firm do not have device history records, which must include finished device testing. Your firm has not established acceptance criteria for the NeedleZap components, such as the housing and copper leads. These devices were manufactured, without your firm preparing and approving a device master record for the NeedleZap. Your firm has not established written device specifications; production process specifications; quality assurance procedures and specifications; final acceptance specifications; and packaging and labeling specifications for the Needle Zap devices.

- failure to establish and implement procedures to control the design of the NeedleZap device in order to ensure that specified design requirements are met (21 CFR 820.30 (a) (1)).

  For example, your firm manufactured the approximately [redacted] NeedleZap devices without a formal design control program being implemented to ensure that the design requirements relating to the device are appropriate and address the intended use of the device, including the needs of the user and patient. No formal design changes were documented and approved, and no design history files were established, for these devices (21 CFR 820.30 (b) through (i)).

- Failure to establish and maintain a quality system that is appropriate for the NeedleZap devices designed and manufactured (21 CFR 820.5).

  For example, a quality system was not established and implemented prior to the approximately [redacted] NeedleZap devices being manufactured and distributed. Your firm has not established written procedures for conducting an audit of the Quality system (21 CFR 820.22). Your firm has not established procedures for identifying training needs and has not ensured that all personnel are trained to perform their assigned responsibilities (21 CFR 820.25 (b)).

You should know that these are serious violations of the law. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Additionally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of class III medical devices. This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president of E-Med Future, Inc., it is your responsibility to assure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

In your response letter dated November 11, 2002, you stated you have recovered 300 NeedleZap devices from a distributor and plan to replace the remaining devices, which are still in commercial distribution, with NeedleZap units manufactured under the

Quality System Regulations after the approval of your PMA. Please be advised that the NeedleZap devices currently in commercial distribution are considered adulterated.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the devices that have been distributed. In addition, please submit any additional documentation to show the corrections initiated in conformance with the requirements of the Quality System Regulation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for class III devices to which the Quality System /GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Your written response to this Warning Letter should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, extension 167, or you may forward a facsimile to her at (513) 679-2773.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District